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WEIZMANN INSTITUTE DRUG, TOOKAD[®] SOLUBLE, APPROVED IN MEXICO FOR PROSTATE CANCER THERAPY

REHOVOT, ISRAEL—January 4, 2016—A therapy invented at the Weizmann Institute of Science and clinically developed in collaboration with Steba Biotech (Luxembourg) has been approved by Cofepris, Mexico’s health authority, for the focal treatment of early-stage prostate cancer.

The therapy involves a laser and a novel drug, TOOKAD[®] Soluble. A successful Phase III clinical trial in Latin America (Mexico, Peru, and Panama), involving 80 patients, confirmed the high rate of local cures and minimal side effects already reported in Phase II clinical trials, as evidenced by negative biopsies and maintenance of patients’ potency, continence, and overall quality of life.

The marketing approval in Mexico comes in the wake of the recent completion of a second Phase III clinical trial in Europe. This randomized pivot study compared disease progression, cancer-free rate, and urinary and erectile functions in patients treated with TOOKAD[®] Soluble and those undergoing active surveillance, with a follow-up of two years. It involved more than 400 patients at 43 hospitals in 11 European countries, and is currently under evaluation by the European Medicines Agency (EMA).

The approved therapy follows a new paradigm – developed by Prof. Yoram Salomon of Weizmann’s Department of Biological Regulation and Prof. Avigdor Scherz of the Department of Plant and Environmental Sciences – in the framework of photodynamic therapy. It comprises an intravenous infusion of TOOKAD[®] Soluble, immediately followed by near-infrared laser illumination through thin optic fibers that are inserted into the cancerous prostatic tissue under ultrasound control. TOOKAD[®] Soluble was first synthesized in Prof. Scherz’s lab from bacteriochlorophyll, the photosynthetic pigment of certain aquatic bacteria that draw their energy supply from sunlight.

The drug stays in the patient's blood for just 3 to 4 hours and shows no toxicity. Confined illumination of the diseased tissue activates the circulating drug locally, resulting in the extensive generation of short-lived toxic molecules: oxygen and nitric oxide radicals. These highly reactive molecules initiate rapid occlusion and destruction of the tumor blood vessels, followed by necrotic death of the entire tumor while sparing nearby structures and their functions. The use of near-infrared illumination, together with the rapid clearance of the drug from the body and the unique non-thermal mechanism of action, makes it possible to safely treat large, deeply embedded cancerous tissues using a minimally invasive procedure. The recent marketing approval was provided to both the drug (TOOKAD[®] Soluble) and the laser illumination device (Laser), together designated Vascular Targeted Photodynamic Therapy (VTP) with TOOKAD[®] Soluble.

In the currently approved focal therapy setting, TOOKAD[®] Soluble VTP (TS-VTP) is an outpatient procedure lasting approximately 90 minutes. Patients are released a few hours later and can return to normal activities within a few days, with none of the side effects frequently associated with prostate removal by surgery or radiotherapy. This new, minimally invasive technology offers a good alternative to patients diagnosed with early-stage prostate cancer. The number of these patients has dramatically increased in the last two decades due to widespread screening of prostate-specific antigen (PSA) levels. This population faces the dilemma of undergoing the radical treatment of prostate removal, which carries the risk of high morbidity, or remaining under active surveillance, with increased risk of further cancer progression.

TOOKAD[®] Soluble answers an unmet need in providing this category of patients with an appropriate treatment that combines good efficacy with preservation of the quality of life.

The Weizmann Institute and Steba Biotech are currently pursuing an extensive oncological research program in collaboration with several clinical groups at Memorial Sloan Kettering Cancer Center in New York City. Four clinical studies for more advanced prostate cancer and other oncological indications stemming from this research are scheduled to start in 2016.

Yeda Research and Development Company, the Weizmann Institute's technology transfer arm, has licensed the drug to Steba Biotech, which manufactures **TOOKAD[®]** Soluble. Amir Naiberg, CEO of Yeda, says: "Our cooperation with Steba covers 20 years of fruitful collaboration. The commitment made by the shareholders of Steba and their personal relationship and effective collaboration with Weizmann Institute scientists and Yeda, have enabled this tremendous accomplishment."

Prof. Yoram Salomon's research is supported by the Principal Anstalt. Prof. Salomon is a Professor Emeritus at the Weizmann Institute. He was the incumbent of Charles and Tillie Lubin Professorial Chair for Biochemical Endocrinology until his retirement in 2009. From the start, Prof. Salomon and Prof. Scherz acted jointly as principal investigators in collaborative research supported by numerous agencies. Prof. Salomon has been a consultant on these projects since 2009.

Prof. Avigdor Scherz's research is supported by the Leona M. and Harry B. Helmsley Charitable Trust; the Thompson Family Foundation, Inc.; the Principal Anstalt; and Sharon Zuckerman, Canada. Prof. Scherz is the incumbent of the Robert and Yadelle Sklare Professorial Chair in Biochemistry.

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